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| 09/641,701 | 08/21/2000 | Yoshinao Kojima | 195870USO | 8831 |

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EXAMINER

PROUTY, REBECCA E

ART UNIT PAPER NUMBER

1652

DATE MAILED: 06/19/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/641,701

Applicant(s)

Kojima et al.

Examiner

Rebecca Prouty

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 10, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above, claim(s) 1-3, 10, and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-6 is/are rejected.
- 7) ☒ Claim(s) 7-9 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

Art Unit: 1652

Applicant's election with traverse of Group II, Claims 4-9 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that coexamination of all claims would not impose an undue burden of search. This is not found persuasive because coexamination of Groups I and II would require the search of subclasses unnecessary for the search of the elected group and thus an undue burden of search would exist.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-3 and 10-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claims 7-9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiply dependent claim and should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claims 4-6 are objected to as depending from non-elected claims.

Art Unit: 1652

Applicant is advised that should claim 5 be found allowable, claim 6 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The recitation of the enzymatic activity in Claim 6 does not further limit Claim 5 as Claim 4 (from which Claim 5 depends) recites a DNA encoding a polypeptide of any of Claims 1-3 and each of the polypeptides of Claims 1-3 recite the same enzymatic activity recited in Claim 6. As such the DNAs of Claim 5 must also encode polypeptides with this enzymatic activity.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 4-6 are rejected under 35 U.S.C. § 101 because the claimed invention is directed toward non-statutory subject matter. In the absence of the hand of man, naturally occurring DNAs are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). This rejection may be overcome

Art Unit: 1652

by amending the claims to contain wording such as "An isolated and purified DNA ..." .

Claims 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 6 are indefinite in the recitation of "stringent conditions" as the specification does not define what conditions constitute "stringent". While pages 15-16 of the specification describes some conditions which are intended to be stringent, there is nothing to suggest that other conditions would not also be included within the scope of this term and in the art what is considered stringent varies widely depending on the individual situation as well as the person making the determination. As such it is unclear how homologous to the sequence of SEQ ID NO:1, a sequence must be to be included within the scope of these claims.

Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1652

These claims are directed to a genus of DNA molecules encoding any Gb3 synthase in view of the inclusion of DNAs encoding polypeptide with substitutions, insertions and deletion in relation to SEQ ID NO:2 in Claim 4 and the recitation that the hybridization of Claim 5 may be to only a undefined part of SEQ ID NO:1. The specification teaches the structure of only a single representative species of such DNAs. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of encoding a Gb3 synthase. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNAs encoding a Gb3 synthase which will hybridize to SEQ ID NO:1 under the conditions described on page 16, lines 1-3, does not reasonably provide enablement for any DNA encoding a GB3 synthase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

Art Unit: 1652

connected, to make the invention commensurate in scope with these claims.

Claims 4-6 are so broad as to encompass any DNA encoding a Gb3 synthase. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of DNAs broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide sequence and encoded amino acid sequence of a single Gb3 synthase gene.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in

Art Unit: 1652

any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of the Gb3 synthase gene of SEQ ID NO:1 because the specification does not establish: (A) regions of the protein structure which may be modified without effecting Gb3 synthase activity; (B) the general tolerance of Gb3 synthases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any Gb3 synthase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any DNA encoding any Gb3 synthase. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ

Art Unit: 1652

19 24 (CCPA 1970)). Without sufficient guidance, determination of DNAs having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 4-6 are rejected under 35 U.S.C. 102(a) as being anticipated by any of Kojima et al. (Reference AF of Applicant's PTO-1449), Steffensen et al. (Reference AE of Applicant's PTO-1449) or Liu et al. (GenBank entry AB041418).

Each of Kojima et al. (AE), Kojima et al. (AF), Steffensen et al. and Liu et al. teach a human gene encoding Gb3 synthase.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 4-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Kojima et al. (Reference AE of Applicant's PTO-1449) or McClaren (GenBank entry Z82176).

Kojima et al. (AE) teach a human gene encoding Gb3 synthase.

Art Unit: 1652

McClaren teach a human clone comprising sequence (bases 30258-32135 of McClaren) 100% identical to the complement of nucleotides 87-1964 of SEQ ID NO:1 and thus encoding all of SEQ ID NO:2.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taniguchi et al. (Reference AH of Applicant's PTO-1449).

Taniguchi et al. teach the purification of rat Gb3 synthase to homogeneity and that this enzyme is responsible for the synthesis of the human P blood group antigen P^k. The many advantages of recombinant production of useful proteins are well

Art Unit: 1652

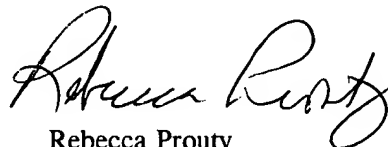
known within the art as are recombinant methods of obtaining the necessary genes. These advantages include the ability to produce much larger quantities of the protein, being able to produce the protein in more easily handled organisms, reducing the number of steps necessary for the purification of a protein and producing the protein in a purer form by using an organism that does not include naturally occurring contaminants of the protein. As such the disclosure of a useful protein, such as that of Taniguchi et al. clearly suggests to the ordinary skilled artisan a gene encoding for the protein as such a gene would be useful to produce large quantities of the protein. Therefore, it would have been obvious to one of ordinary skill in the art to isolate and express the gene encoding the Gb3 synthase of Taniguchi et al. using well known recombinant methods for the isolation of such genes, insertion of the isolated gene into an expression vector, transformation into a suitable host and expression of the encoded protein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Art Unit: 1652

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, appearing to read "Rebecca Prouty".

Rebecca Prouty
Primary Examiner
Art Unit 1652